PATENT
574313-3184.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	F. Pipers
Serial No.	:	09/867,285
Filed	:	May 29, 2001
For	:	OMEPRAZOLE PREVENTION OF ULCERS
Examiner	:	R. Cook
Group Art Unit	:	1644

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April 1, 2005
Date of Signature

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Dr. Michel Riviere, declare and state that:

1. I make this declaration in connection with U.S. application Serial No. 09/867,285. I am familiar with its prosecution history, particularly the Office Action mailed on August 30, 2004.

2. Attached is my Curriculum vitae. In view of my education, training and experience, I consider myself qualified to express opinions stated herein.

3. Claims 34-44 are rejected under 35 U.S.C. Section 103(a) as allegedly unpatentable over Smith in view of WO 96/31213. The Office Action (at 2-3) asserts that Smith

(page 33, columns 1 and 2) "discloses that South American camelids (SACs) are susceptible to ulcers caused by stress" and that "Smith further discloses a method of using omeprazole to prevent gastric ulcers in SACs". While it is acknowledged in the Action that the claims of the instant invention "differ over Smith in reciting prevention of gastric ulcers caused by stress in a horse", the Action maintains that "since horses are also herbivores it would be obvious to one of ordinary skill in the art to use omeprazole in a method for preventing gastric ulcers caused by stress in them. One would have the expectation of success, since Smith discloses that omeprazole can be used to prevent gastric ulcers caused by stress in other herbivores." (Office Action at page 3). It is further stated in the Action that WO 96/31213 discloses the dosage of claim 39 and the oral formulations of claims 43 and 44; and that "once a method of use is known it is within the skill of the artisan to determine optimum dosages and formulations." (Office Action at page 3).

4. The instantly claimed invention provides a method for preventing the occurrence of gastric ulcers in horses about to undergo stress that causes gastric ulcers and prior to the occurrence of gastric ulcer conditions in the horse.

5. Smith, which is concerned with camelids, does not teach or suggest the instant invention which provides a method for preventing the occurrence of gastric ulcers in horses. There are very significant differences in the gastrointestinal physiology of horses and camelids; the fact that omeprazole may or may not have been used to prevent gastric ulcers in SACs would not have led one of ordinary skill to have believed that omeprazole could have been effective in horses. An ulcer condition in a camelid is very different from an ulcer condition in a horse. While both horses and camelids may both be herbivores, they are different types of herbivores: horses are non-ruminant herbivores, while camelids are ruminant herbivores. See "Comparative Digestion and Physiology"(www.avs.uidaho.edu/avs/305/comparative%20digestion.htm; Exhibit 1),and "The Gastrointestinal System:An Introduction" (www.chu.cam.ac.uk/~ALRF/giintro.htm; Exhibit 2).

6. The differences between horse and camelid gastrointestinal physiology reflect the differences in their respective specializations. The physiological mechanisms and anatomical specializations required to support the respective digestive processes are markedly different from each other. For example, the stomachs of horses are specialized for frequent small meals---i.e.,

relatively small and tonic gastric acid secreting (see Tufts Bulletin, at 1, of records in this application).

7. In more detail, horses are monogastric non-ruminant herbivores. The stomach is divided into two distinct regions, the esophageal or non-glandular region (squamous mucosa) and the glandular region. The glandular region, two-thirds of the stomach, contains glands that secrete hydrochloric acid, pepsin, bicarbonate and mucus. Gastric ulcers in foals and adult horses are commonly located in the non-glandular region. However with non-steroidal anti-inflammatory drugs gastric ulcers may be located in the glandular region near the pylorus. Ulcers in the squamous mucosa are primarily due to prolonged exposure to hydrochloric acid, pepsin, bile acids or organic acids since this region lacks well-developed protective factors similar to esophagus. Ulcers in glandular mucosa are primarily due to disruption of blood flow and decreased mucus and bicarbonate secretion as well as prostaglandin inhibition.

8. In horses the mechanical aspects of exercise and the abdominal pressure may be sufficient to provide prolonged exposure of the non-glandular mucosa to aggressive factors. In particular in racehorses that perform at near maximum levels, exercise may have an inhibitory effect on gastric emptying, may decrease gastric and esophageal motility and delay gastric emptying, leading to gastric ulceration. Delayed gastric emptying or decreased gastric motility increase the exposure of the squamous mucosa to gastric juice and other aggressive factors. Omeprazole is an "acid pump inhibitor" inhibiting gastric acid secretion.

9. However, camelids (SACs) are polygastric ruminants. The stomach has three compartments. The first forestomach compartment (C1) where digesta is fermented, eructated, re-swallowed, passed through the second compartment (C2) and the third compartment (C3) before to reach duodenum. C1 is similar to the rumen of the domestic ruminants. C1 and C2 function as fermentation chambers and absorb water and various nutriments. C3, which contains proper gastric glands is acid-, pepsin-, and rennin-secretory and performs gastric digestion. Ulcers in camelids are observed in C3. In ruminants, one can note also the large volume of the rumen.

10. Therefore, it is respectfully submitted that, in view of the differences between horse and camelid digestive physiology and Smith's focus on ulcers in camelids, a skilled artisan would not be motivated to modify Smith to arrive at the instantly claimed invention which provides a method for preventing the occurrence of gastric ulcers in horses about to undergo

stress that causes gastric ulcers and prior to the occurrence of gastric ulcer conditions in the horse.

11. With respect to WO 96/31213, it is noted that this document only relates to compositions comprising proton-pump inhibitors; there is no teaching or suggestion of Applicant's method for the prevention of gastric ulcers prior to the occurrence of gastric ulcer conditions in horses,

12. Therefore, the cited documents do not teach, suggest, or provide motivation for a skilled artisan to practice the presently claimed invention. Accordingly, reconsideration and withdrawal of the obviousness rejection are respectfully requested.

13. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: March 17, 2005

Michel Riviere